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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,347	FEDER ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed	1652	

-- Th MAILING DATE of this communication app ars on the cov r sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-44* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *24,25 and 29-44* is/are rejected.

7)☐ Claim(s) *26 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper ~~No(s)~~ filed 8/12/02 & 8/7/03 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The application has been amended as requested in the communication filed August 7, 2003. Accordingly, claims 1-23 have been canceled, and claims 24-44 have been entered.

Applicant's election without traverse of Group I, orginal claims 1-4, 8, 9, and 16-19 which corresponds to new claims 24-44, in Paper filed August 7, 2003 is acknowledged.

Claims 24-44 are pending.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), see for example page 2, lines 4 and 18. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example page 200, the penultimate line. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 40-44 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40 exapand the scope of independent claim 24. Claim 24 is drawn to the nucleic acid sequences in sections (a)-(f). Sections (a) and (b) recite "a nucleic acid encoding amino acid residues 1-625 and 2-625, respectively, and section (c) and (d) recite a specific nucleic acid sequence comprised in a biological deposites. Section (e) is drawn to a nucleic acid sequence encoding a polypeptide comprising at least 437 contigious amino acid residues of SEQ ID NO: 2 which can be further limited to 80% sequence homology, but claim 40 reads on any of the nucleic acid sequences listed in sections (a)-(f). Thus, claim 40 is improperly dependent on claim 24 because it expands the scope of claim 24. Also, claim 44 does not further limit claim 40 from which it is dependent on. Claims 41-43 are included in the objection because they are dependent on claim 40 and do not cure its deficincies.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification lacks a sufficient written description for enabelment based on deposit requirement.

The invention appears to employ a novel plasmid. Since the plasmid is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be biblically known and freely available. The enablement requirement of 35 U.S.C. § 112 may be satisfied by deposit of the plasmid or transformed. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmid should have been made in accordance with 37 C.F.R. § 1.801-1.809.

Although the specification indicates that the deposits were made under the terms of the Budapest Treaty, the paragraph bridging pages 16 and 17, there is no indication of public availability of the deposits upon issuance of the patent. An affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism(s) has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

Claims 24, 29, 30, and 33-39 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 24 and 31-44 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the nucleic acid sequence encoding the protein of SEQ ID NO: 2 including SEQ ID NO: 1. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to all possible nucleic acid sequences encoding 437 contigious amino acid residues of SEQ ID NO: 2 which has any type of NFKB modulating activities, i. e., icreasing or decreasing of any kind of NFKB (claims 24, 31, and 33-39). Also, claims 40-44 are drawn to any nucleic acid

sequence encoding a protein having 80% sequence homology to SEQ ID NO: 2 having any type of NFKB modulating activities which includes natural and man-made insertion, deletion, substitution and combination thereof mutants. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses enoding any protein having 80% sequence homology to SEQ ID NO: 2 or comprising 437 contigious amino acid residues of SEQ ID NO: 2. The specification provides guidance and examples in the form of an assay to obtain the nucleic acid of SEQ ID NO: 1, and the identification of the open reading frame of the amino acid sequence of SEQ ID NO: 2. From the examiner reading of the 292 pages of the specification, it is concluded that the applicants have identified a nucleic acid sequence encoding a protein with no specific biological or chemical functions. Antisence fragments directed against the coding sequence of SEQ ID NO: 1, however, are shown to increase the level of expression of IκBα, a result consistant with negative regulation of NF-κB/IκBα activity or expression, see the paragraph bridging pages 26 and 27. The phrase IκBα modulating activity in claims 24 and 40 expands the scope of the claimed invention to include variants which positively regulate said activity. The specification has clearly failed to teach one of ordinary skill in the art how to obtain such a variants. While molecular biological techniques and genetic manipulation to make are known in the prior art and the skill of the artisan are well developed, knowledge regarding the actual chemical or biolological function of the protein of SEQ ID NO: 2, assay for the activity(ies) of the polypeptide of SEQ ID NO: 2, the use of variants, and how to obtain a variants the positively increase NF-κB/IκBα activity or expression is lacking. Thus, searching for a specific variant of SEQ ID NO: 2, whether natural or man-made, is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a natural or man-made variant which negatively regulate NF-κB/IκBα activity or expression is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic, cDNA or man-made DNA libraries where the expectation of obtaining the desired protein is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the chemical function or biochemical role of the protein of SEQ ID NO: 2, a chemical or biochemical assay for its activity(ies), structural element required for negatively regulating NF-κB/IκBα activity or expression, and the amino acid sequences which can be inserted in or deleted from SEQ ID NO: 2 without adverse effect to its ability to negatively regulate NF-κB/IκBα activity or expression. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 24, 25, 27, and 33-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

(a) claims 24, 40, and 44 contains the undefined abbreviations and acronyms NFκB. Abbreviations and acronyms must be defined at least once in the claims.

(b) the phrases "amino acid 1 to 625 of SEQ ID NO: 2 including the start codon", "amino acid 2 to 625 of SEQ ID NO: 2 minus the start codon", and "(antisense)" in claim 24, sections (a), (b), and (f), respectively, render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Residues 1-625 of SEQ ID NO: 2 contains already the methionine residue # 1 encoded by the start codon ATG. Similarlly, a nucleic acid sequence encoding the amino acid residues 2-625 of SEQ ID NO: 2 would be missing the start codon deleting the phrases following SEQ ID NO: 2 in sections (a) and (b) would obviate these rejections. The presence of (antisence) in section (f) is confusing because it means the complimentary sequence, but it does not mean neccisserly the entire complementary nucleic acid sequence. The removal of (antisence) would obviate this rejection.

(c) claims 25, 27, 33-39, and 41-43 are included in this rejection because they are dependent on rejected claims and do not cure their deficincies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 24, 25, 27, 29-38, 40-42, and 44 are rejected under 35 U.S.C. § 102(e) as being anticipated by Burford *et al.* (IDS filed August 12, 2002: reference AN, WO 01/42288).

Burford *et al.* teach the nucleic acid sequence of SEQ ID NO: 41 containing 3,365 residues which encods the 891 amino acid residues of SEQ ID NO: 2. The amino acid sequence of SEQ ID NO: 2 taught by Burford *et al.* comprises the amino acid sequence of SEQ ID NO: 2 of the instant application in its entirty. SEQ ID NO: 2 of the instant application corresponds to residues 267-891 of SEQ ID NO: 2 of the amino acid sequence taught by Burford *et al.* Thus, the nucleic acid sequence of SEQ ID NO: 41 taught by Burford *et al.* comprises a nucleic acid sequence encoding residues 1-625 and 2-625 of SEQ ID NO: 2 (section (a) and (b) of claim 24, respectively; the nucleic acid of the deposits of section (c) and (d) of claim 1; and a nucleic acid sequence encoding at least 437 contigious amino acid residues of SEQ ID NO: 2 (claims 24, 25, 27, 29-33, 40 and 44). Also, Burford *et al.* teach a vector comprising and host cells the nucleic acid comprising the above mentioned nucleic acid as well as a recombinant method to make the polypeptide (claims 34-37, and 41), see from page 31, line 12, through page 35, line 27. In addition, they teach the expression of the polypeptide as heterologus fusion protein (claim 38 and 42), see from page 35, line 28-36, line 10.

Claims 26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner